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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,144	01/30/2004	Tibor Keler	CDJ-301	9318

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
07/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/769,144	KELER ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/25/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/23/07 has been entered.

2. Applicant's IDS filed on 9/25/06 is acknowledged.

3. In view of Applicant's amendments to the claims and arguments, the following rejections remain.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 33-37, 39-45 and 47-59 stand rejected under 35 U.S.C. 102(b) as being anticipated by the WO 01/85798 A2 (IDS reference), of record.

The '798 publication teaches an human monoclonal antibody to antigen presenting cell (i.e. dendritic cells) conjugated to tumor antigen (p. 5-6, 54-55, in particular), in vivo and ex vivo internalization of antigen by APC, immune response mediated by MHC-I/II complexes, antibody being Fab and use of immunostimulatory cytokines as adjuvant (i.e. GM-CSF, p. 5-6, 26, 38-41, 56-58, claims 16, 23-27, 32, 38-42, in particular).

The '798 publication further teaches the antibody mediates cytotoxic T cell response (p. 6, 35-36) and antibody comprising claimed SEQ ID NOs: 4 and 8 (example 2, SEQ ID NOs: 2 and 4). As the SEQ ID NOs: 4 and 8 encompass the CDRs identified as in SEQ ID NOs: 13-18, the reference teaching meets the claimed limitation.

Claim 37 is included in this rejection because as evidenced by the specification of the instant application p. 14, lines 14-18, the antibody encompasses the B11, and the referenced antibody teaches B11 (referenced SEQ ID NOs: 2 and 4), binding to a C type lectin on the dendritic cells and human mannose receptor is the inherent property of the of the anti-APC antibody. Therefore, reference teachings anticipate the claimed invention.

Applicant's arguments filed on 5/23/07 have been fully considered but they were not persuasive.

Applicants' traversed the rejection based on that the prior art had not shown the CTL responses mediated by both MHC Class I and Class II pathways and intracellular pathways for MHC Class I and II presentations are completely distinct. Thus one cannot extrapolate from the data of the prior art which pertains to enhancement of MHC Class II presentation.

However, the claimed invention is drawn to a method of inducing cytotoxic T cell response against ant antigen by forming a conjugate of an antigen and a monoclonal antibody that binds to the human macrophage mannose receptor and contacting the conjugate either in vivo and ex vivo with antigen presenting cells. As acknowledged by the instant specification on p. 10 and the applicants' remarks filed on 5/23/07 p.9, the claimed monoclonal antibody that binds to human macrophage mannose receptor refers to human B11 antigen. The referenced antibody produced by the B11 hybridoma that binds to macrophaage mannose receptor (p. 72, claims 32-41, in particular) is identical to the claimed monoclonal antibody.

The identical immune conjugate comprising an antigen and a monoclonal antibody binds to human mannose receptor via the identical method of contacting (e.g. *in vivo* and *ex vivo* internalization of antigen by APC), the mechanism of inducing the cytotoxic T cell response by both MHC Class I and Class II pathways or CD4+ and CD8+ are inherent property of the immune conjugate comprising an antigen and a monoclonal antibody binds to human mannose receptor.

Unlike Applicants' argument that one cannot extrapolate from the data of the prior art which pertains to enhancement of MHC Class II presentation, the '798 publication teaches the cytotoxic and cell killing activity by human monoclonal antibodies to dendritic cells (p. 25-27) pertaining to CD8 activity and MHC Class I presentation. Therefore, reference teachings anticipate the claimed invention.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 33, 38 and 46 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/85798 (IDS reference, of record) in view of U.S. Pat. No. 5,869,057 (IDS reference, of record).

The teachings of the '798 publication have been discussed, supra.

The '798 publication does not teach the use of βhCG as an antigen.

However, the '057 patent teaches the use of βhCG as an antigen (i.e. detectable on the 74 cancer cell lines, col. 3, lines 40-50, col. 5, lines 32-60, in particular) as well as its capacity to present antigen to CD4+ cells (col. 3, lines 25-30, in particular). The '057 patent further teaches that the βhCG is a general tumor antigen which could be using immunization against βhCG as an antimetastasis treatment.

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to substitute the antigen with βhCG as taught by the '057 patent in a method of enhancing an CTL response taught by the '798 publication.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the βhCG is a well characterized tumor antigen as well as its capacity to present antigen to CD4+ cells and the use in immunization as taught by the '057 patent (col. 3, and 5 in particular).

From the teachings of references, it would have been obvious to one of the ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary skill in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed 5/23/07 have been fully considered but they were not persuasive.

Applicants' traversed the rejection based on that the prior art had not shown the CTL responses mediated by both MHC Class I and Class II pathways and intracellular pathways for MHC Class I and II presentations are completely distinct. Thus one cannot extrapolate from the data of the prior art which pertains to enhancement of MHC Class II presentation and the '798 publication is not prior art. Therefore, the combination with the secondary reference does not cure the deficiency.

As discussed above in section 6 of this office action, the '798 publication teaches all the limitations except the use of βhCG as an antigen as in claims 38 and 46.

In light of the discussion above, the '798 publication is a prior art and the combination of teachings remain obvious.

8. No claims are allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
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July 16, 2007

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